**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

| | | |
|---|---|---|
| ENZO BIOCHEM, INC. ET AL., | : | |
| Plaintiffs, | : | |
| vs. | : | 02-CV-8448 (RJS) |
| AMERSHAM PLC, et al., | : | |
| Defendants, | : | |
| AND RELATED CASES NAMING | : | |
| MOLECULAR PROBES, INC., PERKINELMER, INC., PERKINELMER LIFE SCIENCES, INC., ORCHID BIOSCIENCES, INC., AFFYMETRIX, INC., ROCHE DIAGNOSTICS GMBH, AND ROCHE MOLECULAR SYSTEMS, INC. AS DEFENDANTS AND/OR DECLARATORY JUDGMENT PLAINTIFFS, | : | 03-CV-03817 (RJS)<br>03-CV-03819 (RJS)<br>03-CV-03816 (RJS)<br>04-CV-01555 (RJS)<br>04-CV-04046 (RJS)<br>03-CV-08907 (RJS) |
| and | : | **ORAL ARGUMENT REQUESTED** |
| YALE UNIVERSITY, | : | |
| Nominal Defendant. | : | |

**MEMORANDUM IN SUPPORT OF DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT**

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## I. INTRODUCTION

Affymetrix, Inc. ("Affymetrix"), Amersham plc, Amersham Biosciences (collectively "Amersham"), Molecular Probes, Inc. ("MPI"), Orchid Biosciences, Inc. ("Orchid"), PerkinElmer Life Sciences, Inc., PerkinElmer, Inc. (collectively "PE"), Roche Diagnostics GmbH, and Roche Molecular Systems, Inc. (collectively "Roche") jointly submit this memorandum in support of their motion for summary judgment of non-infringement of all of the patents-in-suit.[1] Although there are six defendant groups and many accused products, the issues presented by this motion are relatively narrow. With respect to three of the patents, the Defendants are entitled to summary judgment because the accused products do not satisfy one or more limitations of the claims as interpreted by the Court.[2] With respect to three others, PE and Roche were expressly authorized by distribution agreements with Enzo to sell the accused products.[3] Finally, Enzo's Lanham Act claim asserted against several of the defendants is invalid as a matter of law.

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[1] Absent an indication to the contrary, all of the exhibits referenced herein are attached to the Declaration of Robert J. Gunther, Jr. In Support Of Defendants' Joint Motion For Summary Judgment ("Gunther Decl.") filed herewith. Unless otherwise indicated, all emphasis in this brief has been added.

[2] U.S. Patent Nos. 5,328,824, 5,449,767 and 4,994,373 (the "'824," "'767" and "'373" patents). *See* Ex. 8, '824 patent, Ex. 9, '767 patent, Ex. 10, '373 patent. PE and Roche were also authorized to sell certain of the products accused of infringing one or more of these patents, and therefore have an independent defense applicable to those products.

[3] U.S. Patent Nos. 4,711,955, 4,707,440 and 5,241,060 patents (the "'955," "'040" and "'060" patents). *See* Ex. 11, '955 patent, Ex. 12, '440 patent, Ex. 13, '060 patent. PE and Roche are the only defendants charged with infringing the '040 and '955 patent. PE was also authorized to sell the products accused of infringing the '060 patent.

## II. BACKGROUND

### A. The Technology[4]

#### 1. *Nucleic Acids*

Nucleic acid molecules are fundamental to all life forms. The most well-known nucleic acids are the two fundamental molecules of genetics—DNA (deoxyribonucleic acid) and RNA (ribonucleic acid). Nucleic acid molecules are thread-like molecules that can be either single or double-stranded. Ex. 15, Blackburn Decl., ¶¶15-29, Figures 2-3. DNA, for example, takes a double helix shape when it is in its double-stranded form. Figure 1A is a three-dimensional depiction of the double helix, while Figure 1B shows a flattened out two-dimensional view of a double-stranded sequence. *Id*.

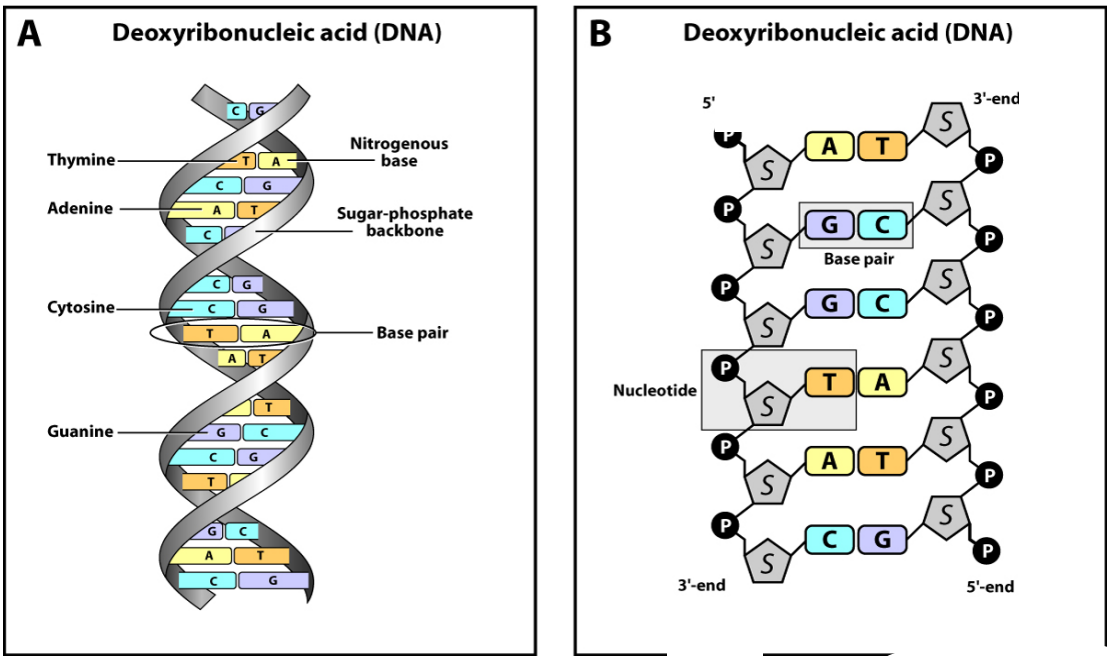


**Figure 1**

[4] The scientific background provided in this brief is drawn from the declarations of Drs. George Stark and Michael Blackburn, submitted during *Markman* proceedings. *See* Ex. 14, Stark Report; Ex. 15, Blackburn Decl.

DNA and RNA are made up of different sequences of four chemical building blocks called "nucleotides." Because nucleic acid molecules are composed of multiple nucleotides, they are also referred to as "polynucleotides." Each nucleotide has three parts shown below: (1) a base; (2) a pentose sugar;[5] and (3) a phosphate. *Id*. at ¶¶17, 26.

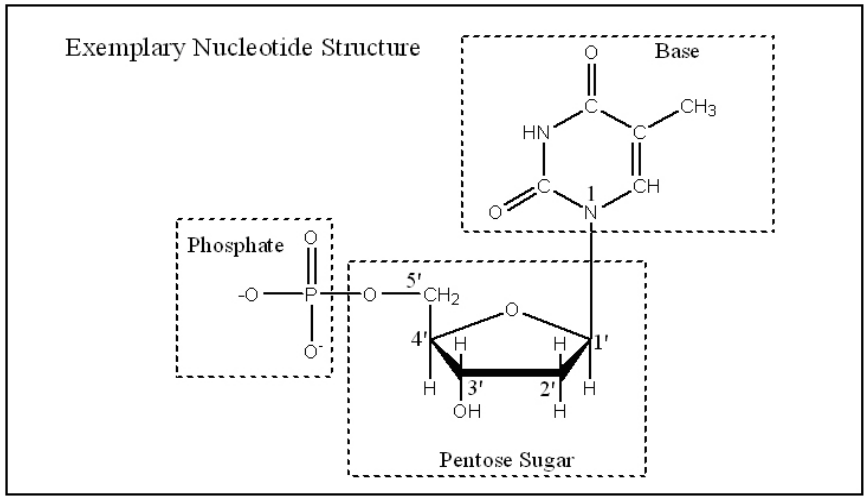


**Figure 2**

Each nucleotide of DNA contains one of four types of bases: adenine ("A"), cytosine ("C"), guanine ("G"), and thymine ("T").[6] Chemically, these four bases are grouped into two general classes, pyrimidines (T and C) and purines (A and G). *Id*. at ¶19.

In order for DNA or RNA to be in a double-stranded form, the sequence of nucleotides in each strand must "pair up," or be "complementary" to one another, with As only pairing with Ts (or Us in RNA) and Gs only pairing with Cs. The base A will only pair with the base T (or U, in RNA), and the base G will only pair with the base C. In Figure 1, for example, the base sequence of the polynucleotide strand on the left, AGGTAC (i.e., from top to bottom) forms base-pairs to the strand on the right which has the base sequence TCCATG (i.e., from top to

[5] A pentose sugar is a sugar molecule composed of five carbon atoms in a ring structure. Ex. 16, Claim Construction Order at 6.

[6] In RNA, the nucleotides are made up of the same A, G and C bases that are in DNA, but with uracil ("U") as the fourth base instead of T.

bottom). In other words, a DNA strand with its specific sequence will only form a double helix with another DNA strand that has a complementary sequence. The pairing up or "binding" of complementary sequences is often referred to as hybridization.

**2. *Nucleic Acid Hybridization Tests***

Since the discovery of the double helix structure, scientists have used the knowledge of base-pairing to develop tests, known as hybridization tests, for detecting whether a specific nucleic acid sequence is present in a biological sample (e.g., a blood sample). As illustrated in Figure 3 below, to carry out a hybridization test, a nucleic acid whose sequence or source is known (e.g., the HIV virus) can be used as a probe to determine whether a blood sample contains a nucleic acid having a complementary sequence. In this example, if the HIV virus probe pairs up or "hybridizes" to the DNA strand in the blood sample, it is likely that the blood sample comes from someone infected by the virus.

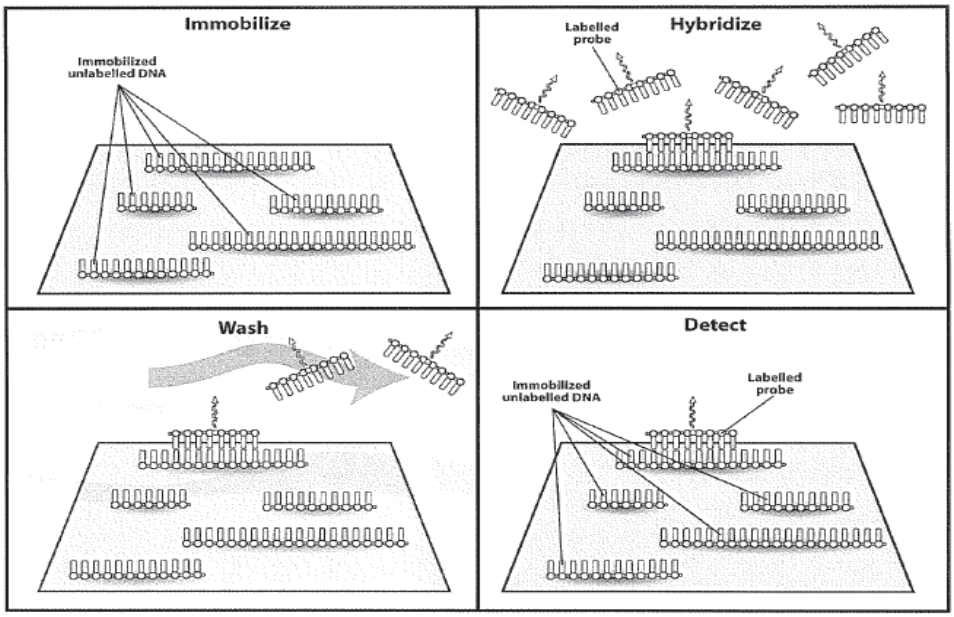


**Figure 3**

Since DNA nucleotides are microscopic, the hybridization of two DNA molecules is difficult to detect unless there is a detectable "label" (or tag) put on the probe. If the probe hybridizes to its complementary strand in the blood sample DNA, the complementary DNA

strand in the blood sample can be identified, based on the labeled probe hybridized to it. Labels can be both directly detectable and indirectly detectable. A directly detectable label is a label on the probe, for example, a fluorescent molecule, that is directly detectable without additional steps. Probes can also be detected indirectly, as when, for example, after an unlabeled probe hybridizes to a target sequence, a labeled molecule that is detectable is introduced into the assay and attaches to the hybridized probe.

Labels have long been commercially available and are used for a wide range of genetic detection purposes. Radioactive atoms have been used to label nucleic acid molecules since the 1950s, and non-radioactive labels have been used for nearly as long. Ex. 15, Blackburn Decl. ¶35.

### B. The Parties

Defendants are leading biotechnology companies that manufacture, market, and/or distribute reagents that can be used to label nucleic acids such as DNA and RNA. Those labeling reagents are sold either separately or as components of tests kits, including diagnostic test kits. Enzo Biochem, Inc. and Enzo Life Sciences, Inc., formerly known as Enzo Diagnostics, Inc. (collectively "Enzo") also manufacture and market labeling reagents. Ex. 6, Roche Amended Compl. ¶ 4. In the 1990s, Enzo entered into distributor agreements with a number of companies, including Roche, Amersham, PE, and Affymetrix, which gave those companies the right to purchase and resell labeling reagents made by Enzo and, in certain instances, allowed them to manufacture their own labeling reagents.[7] *Id*. ¶¶ 5-7.

### C. The Asserted Patents and Accused Products

This motion addresses Enzo's claims that one or more of the defendants are infringing six patents. The '824 and '767 patents, sometimes referred to as the "Ward patents,"[8] are directed

[7] The relevant Roche and PE agreements were entered into by predecessor companies of each: Corange International Ltd. as to Roche and NEN as to PE.

[8] Those two patents are based on the same application. Enzo had previously asserted that certain Defendants were infringing a third Ward patent, the '928 patent. However, that patent was held to be invalid in *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1343 (Fed. Cir. 2010), and is no longer part of this case.

to certain types of non-radioactively labeled nucleotides and methods of using them. Both expired in 2004. The '373 patent discloses a testing method used to determine whether specific nucleic acid sequences are present in a sample. The '373 patent expired in 2009.

Like the Ward patents, the '040, '060 and '955 patents are directed to certain types of non-radioactive labeled nucleotides. However, with respect to these patents, the question presented in this motion is whether the sale of the products accused of infringing those patents was authorized; the specific claims of these patents are not at issue.

**D. Prior Proceedings**

Based on amended interrogatory responses delivered by Enzo on March 9, 2005, Defendants exchanged proposed claim constructions with Enzo, deposed Enzo's *Markman* expert, and conducted other discovery prior to the fact discovery cut-off of May 6, 2005. The claim construction process in this case was comprehensive.[9] In addition to pre- and post-hearing briefing, the Court conducted a five-day *Markman* hearing beginning July 5, 2005, allowed post-hearing briefs, and then held closing arguments. On July 10, 2006, the Court filed its 24-page *Markman* order, which agreed with Defendants on all issues that form the basis of this motion.

In late July 2006, Defendants requested that Enzo amend its patent-related interrogatory responses to identify what allegations remained in the litigation following the claim construction ruling. In September and October 2006, Enzo served amended interrogatory responses. In its responses, Enzo abandoned some earlier infringement allegations, but it also asserted new patent claims against certain Defendants and accused many new products that it had not accused prior

[9] Patent claims are the numbered paragraphs that appear at the end of the patent application. The issue of infringement is decided by comparing the accused product or method to the invention as expressly defined in the patent claims, as these have been interpreted by the Court. The claims are part of a patent's "specification," which includes a more detailed description of the invention, and of the manner and process of making and using it. However, the descriptive language in the specification, while it can be useful in interpreting a claim, cannot expand, modify or override what is in the actual claim language.

to the *Markman* proceedings.[10] At a conference on October 26, 2006, the Court ruled that Enzo must bring a new case if it intended to assert different claims or accuse additional products. Ex. 17, 10/26/06 Tr. at 25. Enzo did not do so.

In early 2007, the Defendants filed a joint summary judgment motion on certain issues common to the individual complaints. Judge Sprizzo did not rule on the motion prior to reassignment of the case. After the case was reassigned, the motion was denied without prejudice. Leave to refile the motion was subsequently granted. In the summary judgment motion filed today, Defendants address those products against which Enzo asserted specific patent claims in its March 2005 interrogatory responses,[11] with the exception of the patent claims and products that Enzo abandoned in September and October 2006.

## III. LEGAL STANDARDS

"[S]ummary judgment is equally appropriate in a patent case as it is in any other type of case." *Affymetrix, Inc. v. PE Corp.*, No. 01 Civ. 0634 (NRB), 2002 WL 31875401, at *5 (S.D.N.Y. Dec. 24, 2002); *Spectra Corp. v. Lutz*, 839 F.2d 1579, 1581 n.6 (Fed. Cir. 1988).

As the Court has already construed the scope of the applicable patent claims, the infringement analysis requires only a determination of whether the accused patents satisfy each element of the construed claims, either literally or under the doctrine of equivalents. *See Bai v. L*

[10] As set forth in Exhibit 18, Enzo limited its patent infringement allegations against Orchid to the '928 and '824 patents and abandoned any allegations under the '767 patent. With the '928 patent declared invalid, only the allegations against Orchid under the '824 patent remain. Orchid, as a purchaser from PE of certain AcycloPrime products, adopts and joins in PE's arguments.

[11] As set forth in the Declaration of Eric M. Jaegers, attached as Exhibit 19, Enzo abandoned its claims as to several of MPI's ARES™ kit products in amended interrogatory responses served in September 2006. However, at the same time Enzo attempted to assert new claims against the individual kit components. In light of the Court's ruling at the October 26, 2006 conference, Enzo cannot now assert new claims against the individual components of the ARES™ kits. Nevertheless, out of an abundance of caution, MPI addresses all of the accused ARES™ products and their accused components herein. Further, in accordance with the Court's instruction, MPI does not address the invalidity of the '060 patent in this motion and, although MPI maintains that its accused products do not infringe the '060 patent, for clarity MPI confirms it is not moving for summary judgment of non-infringement of the '060 patent in this motion.

*& L Wings, Inc*., 160 F. 3d 1350, 1353 (Fed. Cir. 1998). In order to prevail on an assertion of literal infringement, the patentee must establish that every single limitation of its patent claim is met by the accused product. *See Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). If even one limitation is missing or is not met as claimed, there is no literal infringement. *Id.* Summary judgment of no literal infringement should therefore be granted where there is no genuine dispute that the accused product lacks at least one claim limitation. *See Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998).

In certain instances, an accused product may infringe a patent claim under the doctrine of equivalents, but only where the accused product contains every element of a patent claim or an equivalent of that element. *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997). An element in an accused product is considered "equivalent" to a claim limitation only if the differences between the two are insubstantial. *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1331-32 (Fed. Cir. 2001). One relevant test of equivalence is the three part "function-way-result test" that requires the purportedly equivalent feature in the accused product to (1) perform substantially the same function (2) in substantially the same way (3) to obtain the same result as the literal claim limitation. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001). The fact that an accused feature performs the same function as a missing limitation is not enough to demonstrate equivalence. *See, e.g.*, *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1311 (Fed. Cir. 1998) (finding no infringement under doctrine of equivalents because the accused device operated in a "substantially different way"). Summary judgment of non-infringement under the doctrine of equivalents is appropriate where there is no genuine dispute that the differences between a claim limitation and accused product feature are substantial, or where application of the doctrine of equivalents is precluded due to one of the limiting principles stated below. *See Bai*, 160 F.3d at 1353-54.

The Supreme Court has recognized a number of legal limitations on the application of the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997). These "legal limitations . . . are to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." *Id*. (emphasis added). In this case, there are three relevant "legal limitations" to the doctrine of equivalents: (1) the "all-elements rule," which bars a patentee from asserting "a theory of equivalence [that] would entirely vitiate a particular claim element," *id.*; (2) "prosecution history estoppel," which bars a patentee from asserting a scope of equivalency surrendered during prosecution of the patent in the Patent Office, *id*.; and (3) the so-called "disclosure/dedication principle." *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1358-60 (Fed Cir. 2004).

The "all-elements rule" derives from the foundational principle of patent law that an accused product or process cannot be infringing unless it contains each limitation of the claim, either literally or by an equivalent. *See, e.g.*, *Warner-Jenkinson*, 520 U.S. at 29, 117; *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1357-62 (Fed. Cir. 2005). This principle has two primary implications for the doctrine of equivalents. *First*, the all elements rule requires that equivalence be assessed on a *limitation-by-limitation* basis, and not from the perspective of the invention as a whole. *Warner-Jenkinson*, 520 U.S. at 29; *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987) (en banc). *Second*, an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation. *Warner-Jenkinson*, 520 U.S. at 29 ("It is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1017 (Fed. Cir. 2006) ("the 'all elements' rule forecloses resort to the doctrine of equivalents because, on the facts or

theories presented in a case, a limitation would be read completely out of the claim—i.e., the limitation would be effectively removed or 'vitiated.'").

A corollary to the all elements rule is the "specific exclusion" principle. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996). For example, if a patent states that the claimed device must be "non-metallic," the patentee cannot assert the patent against a "metallic" device on the ground that a metallic device is equivalent to a non-metallic device. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346-47 (Fed. Cir. 2001). Under those circumstances, "metallic" devices are deemed to be specifically excluded from the scope of the claims. *Id.* "The unavailability of the doctrine of equivalents could be explained either as the product of an impermissible vitiation of the 'non-metallic' claim limitation, or as the product of a clear and binding statement to the public that metallic structures are excluded from the protection of the patent." *Id.* at 1347.

The all elements rule and the specific exclusion principle have been applied in numerous other cases. *See, e.g., Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (a "minority" cannot be equivalent to a claimed "majority"); *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) ("not mounted" cannot be equivalent to a claimed "mounted"); *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005) ("indirect" cannot be equivalent to "direct"); *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1560-61 (Fed. Cir. 1997) (a "reactive" gas cannot be equivalent to a claimed "inert" gas).

The second legal doctrine precluding the application of the doctrine of equivalents is the doctrine of "prosecution history estoppel." During the back and forth with the Patent Examiner, if a patentee narrows a claim either by argument or amendment in order to satisfy a requirement for patentability, the patentee cannot later assert that the surrendered subject matter is covered under the doctrine of equivalents. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002). In other words, when an applicant limits the scope of a claim in order

to secure allowance of the patent, the patentee is precluded from a later effort in litigation to recover what was previously yielded. *See Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005).

Finally, subject matter disclosed in a patent but not claimed is considered dedicated to the public and cannot be reclaimed through the doctrine of equivalents. *PSC Computer*, 355 F.3d at 1358-60. The "disclosure-dedication" rule is also concerned with the public notice function of patent. "A patentee may not write narrow claims for allowance by the PTO and subsequently attempt to broaden the claims in court by using the doctrine of equivalents." *Id.*; *Autogiro Co. of Am. v. United States*, 181 Ct. Cl. 55, 60, 384 F.2d 391, 396 (1967) ("Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth."). Like the all elements rule and prosecution history estoppel, the "disclosure-dedication" rule also presents a question of law for the Court to decide on summary judgment. *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004).

## IV. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT ON ENZO'S PATENT INFRINGEMENT CLAIMS

This memorandum presents seven arguments, summarized below.

1. As construed by the Court, claim 42 of the '767 patent and claim 1 of the '824 patent require that the label be a single part of a multi-part "signaling moiety" that is indirectly, not directly, detected. The accused products having a fluorescent label that is directly detected and that is not part of a larger moiety do not infringe these claims. *See* Section IV.A.

2. As construed by the Court, claim 42 of the '767 patent and claim 1 of the '824 patent are limited to products that utilize naturally occurring nucleotides having a pentose sugar. Accused products lacking a pentose sugar do not infringe these claims. *See* Section IV.B.

3. Claim 42 of the '767 patent and claim 1 of the '824 patent require an "A" group (which acts as a label) attached to a nucleotide base "B" at a specified position. Accused products lacking a nucleotide base "B" do not infringe these claims. *See* Section IV.C.

4. Claim 1 of the '824 patent requires a phosphate group at the third position of a nucleotide's sugar. Products that lack this phosphate group do not infringe claim 1. *See* Section IV.D.

5. As construed by the Court, all of the asserted claims of the '373 patent are limited to tests in which (a) the "analyte" (not the probe) is affixed to a solid support, (b) the probe (not the analyte) is labeled, and (c) detection occurs via a "soluble signal." Products in which unlabeled probes (rather than analytes) are fixed to the solid support and in which detection is not through a soluble signal, do not meet these claim requirements and therefore do not infringe the '373 patent. *See* Section IV.E.

6. Roche and PE were expressly authorized by their distribution agreements to sell specifically identified products, which Enzo now contends infringe various patents in suit. None of these products can be found to infringe because their manufacture and sale was authorized. *See* Section IV.F.

7. Enzo's allegation that the defendants committed a Lanham Act violation by failing to identify Enzo's patents in their marketing materials is insufficient as a matter of law. *See* Section V.

### A. Products With Directly Detectable Labels Do Not Satisfy The "A" Limitation ('824 Claim 1, '767 Claim 42)

#### 1. *Technical Background Of The Ward Patents And The Relevant Features Of The Accused Products*

The chemical groups used in early non-radioactive labeling tended to be relatively large and bulky and could interfere with hybridization of a probe to its target. One "indirect detection" labeling method attempts to avoid this problem by using a multi-component label. In such a system, a small "handle" is attached to the probe that hybridizes with the target molecule. The handle does not interfere with hybridization to the target sequence and neither the probe nor the handle is directly detectable. Rather, after the probe hybridizes to the target sequence, the handle is designed to bind with a larger molecular complex that is detectable. The handle and the larger

detectable molecular complex thus make up a "multi-component" label. Ex. 15, Blackburn Decl., ¶44.

An example of this indirect detection method is shown in Figure 4 below where a relatively small compound called biotin is attached as a "handle" to a DNA probe. After the probe hybridizes with a complementary DNA strand, the much larger molecule streptavidin, to which other detectable molecules (e.g., fluorescent molecules) have been attached, binds to the biotin molecule. By adding the bulky detectable molecule (streptavidin and the attached fluorophors in Figure 4) after the hybridization, the much smaller biotinylated probe can hybridize to its complementary strand without interference which would otherwise be caused by the streptavidin molecule.

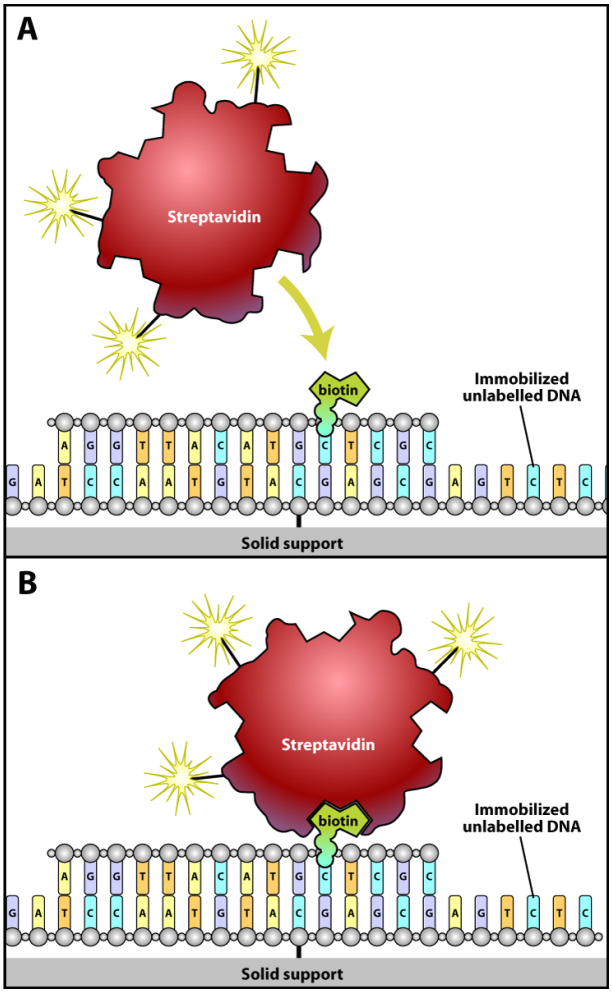


**Figure 4**

The Ward patents are based on a single application which describes methods for implementing this kind of indirect detection method through the attachment of indirectly detectable labels (referred to in the patents as "A") to certain positions on nucleotide bases (referred to in the patents as "B") to probes.

In contrast to the indirect detection method claimed by the Ward patents, the products accused of infringement utilize a single component label that is directly detectable. Specifically, each of the accused products has a fluorescent label attached to the nucleotide base. The fluorescent label emits light that can be directly detected. There is no other component of the label and no second step to the probe hybridization detection process.

**2. *Defendants Are Entitled To Summary Judgment Of No Literal Infringement***

The claim at issue reads in relevant part as follows: "A" . . . "represents at least one component of a signaling moiety capable of producing a detectable signal." Ex. 8, '824 claim 1, Ex. 9, '767 claim 42. During *Markman* proceedings, Plaintiffs argued that "A" could be the sole component of the signaling moiety and could be directly detectable. Ex. 16, Claim Construction Order at 9. Defendants argued that (1) "A" represented only one component of a signaling moiety, but not the whole signaling moiety, and (2) that the claim excluded directly detectable labels. *Id.*

The Court agreed with Defendants, construing the claim language to require that "'A' be one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide." *Id.* at 23. In reaching this construction, the Court explained that the claim language itself "simply does not support plaintiff's position." *Id.*

In light of the claim construction ruling, Amersham, MPI, Orchid and PE are entitled to summary judgment that the accused products set forth on Exhibit 23 do not infringe '824 claim 1 and '767 claim 42. There is no dispute that the accused products all include a directly detectable

fluorescent label.[12] For each accused product, the fluorescent label operates alone and produces a directly detectable signal without the addition of other chemical groups; it is thus not "one component of a *multi-component* signaling moiety,"[13] nor part of a moiety which can only be detected indirectly "via an attached polypeptide."[14] Ex. 16, Claim Construction Order at 9-10, 23.

### 3. *Defendants Are Entitled To Summary Judgment Of No Infringement Under The Doctrine Of Equivalents*

Defendants Amersham, MPI, Orchid and PE are also entitled to judgment of non-infringement under the doctrine of equivalents. No reasonable jury could find that a directly detectable label and an indirectly detectable label are equivalent, i.e., that their differences are insubstantial. *See DeMarini*, 239 F.3d at 1331-32. As the Court has already addressed, there is a marked distinction between a product with a "directly detectable signal" that results when the moiety "itself could be detected" and the "indirectly detectable signal" required by the construed claims that "would result where the component which later attached itself to 'A' was responsible for the generation of the detectable signal." Ex. 16, Claim Construction Order at 9-10.

The significant differences are confirmed by an application of the function-way-result test. *Telemac*, 247 F.3d at 1330. The function of the "A" group is to form a stable complex with a detectable polypeptide which then results in a detectable signal. Ex. 27, Blackburn SJ Decl., ¶¶143-45.[15] In contrast, the function of the fluorescent label is to itself be detectable. Further, the system

[12] Ex. 24, Burczak Decl., ¶¶11, 26, 30, 33-34, 37-38, 43, 45, 48, 50; Ex. 25, Mayer Decl., ¶¶20-21; Ex. 26, Singer Decl., ¶¶19-21.

[13] Ex. 24, Burczak Decl., ¶33, 37, 45, 50, 55; Ex. 25, Mayer Decl., ¶21; Ex. 25, Singer Decl., ¶21.

[14] Ex. 24, Burczak Decl., ¶33, 37, 45, 50, 55; Ex. 25, Mayer Decl., ¶21; Ex. 25, Singer Decl., ¶21.

[15] A three-carbon group within the accused products that Enzo also alleges (belatedly) satisfies the claimed "A" group likewise has a substantially different function (serving as part of the spacer that provides distance between the fluorescent dye and the nucleotide), way (providing a chemical linkage) and result (distance) as that of the claimed "A" group described above. Ex. 27, Blackburn SJ Decl., ¶¶154-55.

claimed under the patent works by indirect detection. The accused system works by direct detection.

A finding of equivalents is also precluded because it would improperly eviscerate the claim language "A . . . represents at least one component of a signaling moiety." Ex. 16, Claim Construction Order at 9-10; *see, e.g.*, *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003). Such a finding would need to find opposites to be equivalent – a direct detection method would be equivalent to an indirect one, and a single component label would be equivalent to a multi-component label. Under the all-elements rule, such an argument is legally impermissible because the direct detection method is specifically excluded from the scope of the claims. *Seachange Int'l*, 413 F.3d at 1378 ("indirect" cannot be equivalent to "direct"); *Eastman Kodak Co.*, 114 F.3d at 1560-61 (a "reactive" gas cannot be equivalent to a claimed "inert" gas).

### B. Products Lacking A Pentose Sugar Do Not Satisfy The "Oligo- Or Polynucleotide" Requirement Of Claim 42 Or The Expressly Depicted Sugar Structure Of Claim 1 ('824 Claim 1, '767 Claim 42)

#### 1. *The Court's Claim Construction*

Claim 42 of the '767 patent covers an "oligo-or polynucleotide sequence" (i.e., more than one nucleotide). During *Markman* proceedings, the parties disputed whether this phrase limited the claim to compounds consisting of naturally occurring nucleotides which, by definition, include a "pentose sugar."[16] Judge Sprizzo expressly rejected Enzo's contention that a "nucleotide" does not require the presence of a pentose sugar and, agreeing with the Defendants,

[16] As noted above and shown in Figure 5 below, a pentose sugar is a cyclical structure having five carbon atoms to which a phosphate group and nitrogenous base are attached.

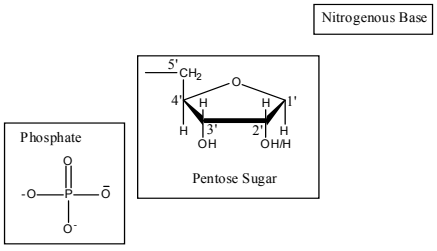


**Figure 5**

construed the terms "nucleotide," "oligonucleotide" and "polynucleotide" to require "naturally occurring nucleotides which have been modified solely by the addition of at least one label 'A' to nitrogenous base 'B.'" Ex. 16, Claim Construction Order at 6-8, 22-23.

Claim 1 of the '824 patent is similarly limited. The initial element of the claim depicts the structure of the nucleotides it covers, including the pentose sugar:

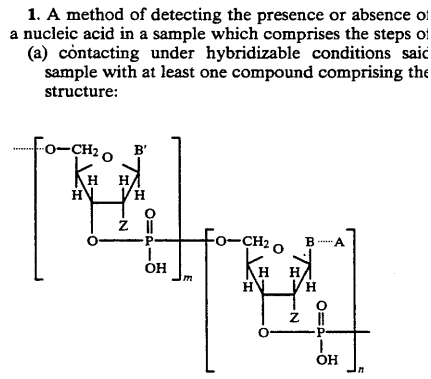


**Figure 6**

The parties did not ask Judge Sprizzo to interpret this element of Claim 1 of the '824 patent because there are no valid grounds for disputing that the claim is limited to the depicted nucleotides.

### 2. *PE's AcycloPrime Products Lack A Pentose Sugar*

PE is entitled to summary judgment that the accused AcycloPrime products set forth in Exhibit 28 do not infringe claim 42 of the '767 patent or claim 1 of the '824 patent because the products do not include naturally occurring nucleotides. Rather, the AcycloPrime products contain a molecule that PE calls an "acycloterminator." As shown in the diagram below, an acycloterminator does not have the five carbon ring structure of a pentose sugar that is required by the claims.

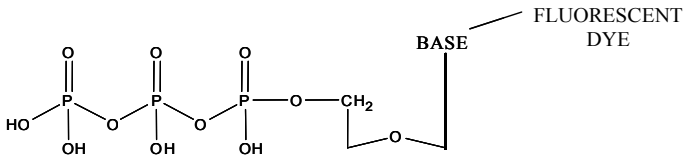


**Figure 7**

They also lack the phosphate group expressly required by claim 1 of the '824 patent.[17] There is no dispute about those facts.

In the prior summary judgment briefing, Enzo did not claim that the AcycloPrime products literally infringe the claims of the '767 and '824 patents; rather it relied solely on the doctrine of equivalents. However, Enzo cannot carry its burden of demonstrating that the differences between the missing limitations of the claims and the structure of the accused acycloterminators is insubstantial. Even if it could, any such contention is barred by the all-elements rule and prosecution history estoppel.

As discussed above, the all-elements rule precludes a finding of infringement under the doctrine of equivalents when such a finding would vitiate a claim limitation. Here, the Court found that the nucleotides covered by the '767 and '824 patents must be "naturally occurring nucleotides which have been modified ***solely*** by the addition" of a labeling component. Ex. 16, Claim Construction Order at 22-23. A finding of infringement by a molecule that had been ***additionally*** modified by removing the pentose sugar and inserting a different element would vitiate this claim limitation. *See Durel Corp. v. Osram Sylvania, Inc.,* 256 F.3d 1298, 1305 (Fed. Cir. 2001). ("As we have construed the claims, the 'oxide coating' must primarily comprise binary compounds containing only metal cations and oxygen. Sylvania's AlO(OH) and Al(OH)3 coatings contain an additional element, hydrogen, and therefore do not meet the claim limitation . . . . A finding of equivalence would vitiate the limitation 'oxide coating,' which we have concluded is defined to primarily consist of a binary compound.").

Prosecution history estoppel also precludes a finding of equivalence. Not once but twice, Enzo expressly told the Patent Office that its invention was characterized by the labeling of ***nucleotides*** to distinguish prior art showing the labeling of other types of molecules. During

[17] The acycloterminators do not infringe the asserted claims of the Ward patents for the additional reason that they do not utilize an indirectly detectable label. *See supra,* Section IV.A. Orchid, as a purchaser from PE of certain AcycloPrime products, joins in and adopts PE's arguments above and *infra*.

prosecution of the original Ward application that led to the '767 patent, Enzo rebutted a rejection by the PTO based on obviousness by arguing '[t]hat the references (Bergstrom and Ruth) are only directed to pyrimidine **nucleosides**" (which differ from nucleotides in not having a phosphate group) and there "is absolutely no teaching or suggestion in any of these references of ***nucleotides*** or chemically labeled ***nucleotides***" Ex. 19, at 3. Based on this distinction, Enzo then argued to the PTO that "[i]t is not seen how one skilled in the art having the disclosures of these references in view would come away with any teaching or suggestion of applicant's claimed invention which is ***nucleotide***-based." *Id.*

Similarly, in another parent application which matured into the '955 patent, Enzo distinguished the claimed subject matter over certain prior art references on the basis that the earlier references disclosed molecules that, like the acycloterminators, lacked the sugar component of a nucleotide. Enzo argued that the references "do not refer to or suggest applicants' ***nucleotides*** because they only refer to bases without sugars." Ex. 30, at 26. These arguments estop Enzo from now relying on the doctrine of equivalents to cover acycloterminators, which are indisputably not nucleotides ***because they lack a pentose sugar***. *See, e.g.*, *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.,* 170 F.3d 1373, 1377 (Fed. Cir. 1999) (estoppel applied to bar finding of equivalents to claim limitation used to distinguish prior art).

### 3. *PE Is Not Estopped From Arguing Non-Infringement*

In its prior briefing, Enzo also attempted to convince the Court that PE was estopped from contesting non-infringement by a provision of a settlement agreement between PE's predecessor, a company called NEN, and Enzo, in which NEN stipulated that multiple Enzo patents were valid, dominated certain NEN patents and were previously violated by some NEN products. Enzo's estoppel argument is without merit for three reasons.

*First*, the ENZO-NEN Distributorship Agreement executed at the same time as the settlement agreement expressly and unequivocally provided that all of NEN's stipulations

relating to the Enzo patents, whether in the settlement agreement or any other agreement, would be rendered "null and void" upon termination of the Distribution Agreement. Ex. 31, PE Agreement § 15. The Distributorship Agreement was terminated by PE in December 2004. Ex. 44, LeBlanc Decl., ¶11.

*Second*, NEN's acknowledgement of "infringement" or "domination" did not address any specific NEN product or Enzo patent. In fact, in the Distributorship Agreement between the parties that was part of the settlement, hundreds of NEN products (but not acycloterminators) and dozens of Enzo patents are identified. Thus, no conclusion can made about any particular product or patent based on NEN's general statements regarding infringement.

*Third*, the Court's construction of the claims (which, of course, was not available at the time the Settlement Agreement was executed), the all-elements rule and prosecution history estoppel are all issues of law. There is no factual dispute about the structure of the accused acycloterminators. Whatever their evidentiary value, NEN's statements are clearly insufficient to defeat summary judgment. General and conclusory statements about the infringement of unidentified patents by unidentified products are insufficient to create a genuine issue of disputed fact on the issue of infringement. *See Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.,* 123 F.3d 1445, 1454 (Fed. Cir. 1997) (conclusory admissions of defendants' scientists insufficient to defeat summary judgment).

### C. Products Without A Nucleotide Base Attached To "A" Cannot Satisfy The Claimed Requirements ('824 Claim 1, '767 Claim 42)

Roche is entitled to summary judgment that its DIG 5' End Labeling Sets do not infringe '824 claim 1 or '767 claim 42.[18] In its prior briefing on the issue, Enzo failed to argue that those Roche products infringe the asserted claims, thereby conceding that summary judgment is appropriate on the grounds set forth in the Defendants' joint motion.

[18] Enzo elsewhere refers to this same product as the "Genius 5' End Labeling Sets."

It is not surprising that Enzo failed to argue infringement, since there is no literal infringement on several independent grounds. *First*, both asserted Ward patent claims require a nucleotide base "B," which is defined as a 7-deazapurine or pyrimidine moiety. *See* Ex. 8, '824 claim 1, Ex. 9, '767 claim 42. The DIG 5' product does not meet this requirement, because it contains no nucleotide base "B". Ex. 32, Will Decl., ¶¶7-8. *Second*, both asserted claims require an "A" group attached to the nucleotide base "B" at a specified position. *See* Ex. 8, '824 claim 1, Ex. 9, '767 claim 42. But the DIG 5' product contains no nucleotide base "B" to which the "A" group must be attached. *Third*, when the DIG 5' product is used to label an oligonucleotide, the label is not attached to any base position, as required by the asserted Ward claims. Ex. 32, Will Decl., ¶¶7-8. Instead, the label is attached to the 5' end of the sugar. Ex. 33, Exhibit 18 of Enzo's March 9, 2005 Responses to Roche Interrogatories.

Nor could the DIG 5' product infringe under the doctrine of equivalents. To argue that a sugar group is equivalent to a base would completely vitiate the claim language requiring that the "A" group be attached to the nucleotide base "B". *See Warner-Jenkinson*, 520 U.S. at 39 n.8. A nucleotide base "B" is an entirely different and distinct structure from the pentose sugar structure found in a nucleotide. Ex. 15, Blackburn Decl., ¶17. Moreover, during prosecution Enzo repeatedly emphasized the novelty of the attachment of the "A" group to not only a nucleotide base "B", but to specific positions on the nucleotide base "B". *See, e.g.*, Ex. 30 at 10, 15, 18-19. Thus, Enzo's own representations to the Patent Office establish that to allow the asserted claims to cover attachment of the "A" group to a pentose sugar under the doctrine of equivalents would vitiate the requirement that a nucleotide base "B" must be attached to the "A" group at specific positions.

### D. Dideoxynucleotides Do Not Satisfy The 3' Phosphate Requirement ('824 Claim)

Claim 1 of the '824 patent requires use of a nucleic acid polymer structure with a phosphate group attached to the 3' position of the labeled nucleotide as indicated by the blue arrow below. Ex. 8, '824 patent col. 30:55-31:10. Blackburn Decl., ¶156.

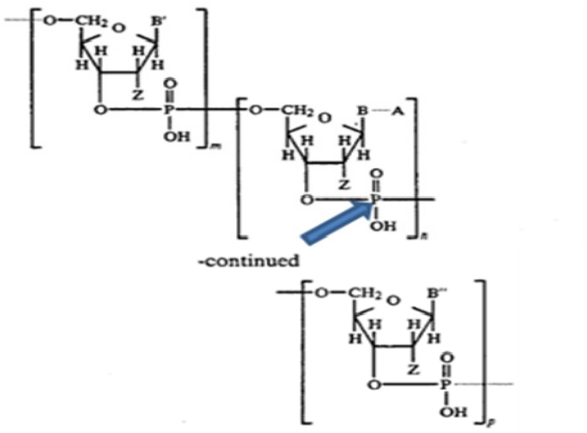


**Figure 8**

Enzo now argues that this claim is not limited to products with the claimed structure. But Enzo is not permitted to rewrite unambiguous patent claim language. *Chef Am., Inc., v. Lamb-Weston, Inc.,* 358 F.3d 1371, 1375 (Fed. Cir. 2004). There is no suggestion from the face of the patent or the prosecution history that the patentee made an error, let alone an obvious and correctable error. *CBT Flint Partners, LLC, v. Return Path, Inc.,* Nos. 2010-1202, 2010-1203, 2011 WL 3487023, at *9 (Fed. Cir. Aug. 10, 2011). Thus, the claim must stand as written.

The Exhibit 34 accused products cannot meet the claim limitation because they are dideoxynucleotide monomers, which means that they have a hydrogen atom at the 3' position, instead of the phosphate group required by claim 1. Ex. 27, Blackburn SJ Decl., ¶157; Ex. 24, Burczak Decl., ¶24; Ex. 25, Mayer Decl., ¶25.[19] This is not an insubstantial difference. When a dideoxynucleotide monomer is used to make a DNA polymer, the 3' hydrogen acts as "a wrench in the gears" that prevents another nucleotide, or any other chemical group, from being attached to the 3' polymer end. *See* Ex. 27, Blackburn SJ Decl., ¶158, Ex. 24, Burczak Decl., ¶24; Ex. 25, Mayer Decl., ¶26.

[19] In prior summary judgment briefing, Enzo alleged that PE infringed claim 1 of the '824 patent in making and selling acycloterminators, although this contention was not made in its March 9, 2005 answers to interrogatories. To the extent Enzo is allowed to pursue this contention at this stage in the proceedings, it is meritless. Both the carbon at the '3 position of the pentose sugar of a nucleotide ***and*** an attached phosphate are missing from the structure of the acycloterminators.

Because a dideoxynucleotide monomer terminates DNA polymer strand growth, the accused labeled dideoxynucleotide monomers are always the final nucleotide at that end of a DNA strand, i.e., the end of the string. Ex. 27, Blackburn SJ Decl., ¶158, Ex. 24, Burczak Decl., ¶24; Ex. 25, Mayer Decl., ¶¶25-26. Thus, it is impossible for these accused products to be extended with the result that the final structure has a phosphate group attached at the 3' position as required by the claim. *See* Ex. 27, Blackburn SJ Decl., ¶¶157-58.

The accused Exhibit 34 products also cannot infringe '824 claim 1 under the doctrine of equivalents. First, to find otherwise would improperly require rewriting the claimed chemical structure and thus vitiate the 'phosphate group requirement'. *See Lockheed*, 324 F.3d at 1321. Second, there are substantial differences between the chemical structure resulting from the accused dideoxynucleotide products, which have a 3' hydrogen atom, and the claimed chemical structure, which requires a 3' phosphate group. Ex. 27, Blackburn SJ Decl., ¶¶158-59. Most significantly, because the 3' hydrogen atom of the accused products prevents any further extension of a DNA polymer strand, dideoxynucleotides can be used in a specific type of sequencing method requiring chain termination, while nucleotides of the type claimed by Enzo cannot be used for this purpose. *Id.* ¶158. Thus, the accused dideoxynucleotide products provide both a substantially different function and result (i.e., chain termination) and a substantially different chemical structure than the claimed structure. *See id.* ¶¶158-59; *see also Telemac*, 247 F.3d at 1330.

### E. Products Using Neither The Format Nor The Soluble Signal Required By The '373 Patent Claims Cannot be Infringing

Affymetrix, Amersham, PE and Roche are entitled to summary judgment that the accused products set forth in Exhibit 35 do not infringe the asserted '373 patent claims on two independent grounds. *First*, the accused products do not employ the specific test format required by the claims, whereby the probe (not the sample) must be labeled and the sample (not the probe) must be fixed to a solid support (the "format" requirement). *Second*, the accused products do not

satisfy the "soluble signal" limitation because each of the accused products utilizes a tethered fluorescent molecule which the Court expressly found to be outside the scope of the claim.

### 1. *Technical Background Of The '373 Patent And The Relevant Features Of The Accused Products*

#### a) The Claimed Nucleic Hybridization Assay

The '373 patent discloses a testing method used to determine whether specific nucleic acid sequences, referred to in the patent as "analytes," are present in a sample such as blood or saliva. The claimed testing method is straightforward: single-stranded nucleic acid sequences obtained from the sample are fixed to a solid support. Labeled probes consisting of single-stranded nucleic acid sequences that are complementary to the analyte of interest are then introduced in a solution. If the analyte being searched for is present in the sample, the probe will hybridize (i.e., bind) to the analyte and will remain attached (via the analyte) to the solid support after a "washing" step. *See, e.g.*, Ex. 14, Stark Report ¶¶ 44-46; Ex. 16, Claim Construction Order at 18-19. If the probes do not hybridize, they will be removed by the washing step.

The labeling and detection technique disclosed in the '373 patent was adapted from a prior technique that uses an enzyme molecule as the nonradioactive label. An enzyme is a type of protein that causes the chemical transformation of another chemical compound in a solution. Typically, a particular enzyme transforms a specific chemical compound, referred to as the "substrate," by binding to the substrate and then making or breaking a specific chemical bond in it. The enzyme thereby creates one or more new chemical compounds called "products" with chemical structures that differ from that of the original substrate. The new chemical products are transformed in a manner that makes them readily detectable, e.g., as a colored product.

Because molecules of the detectable product are released into the surrounding solution, products that are colored under certain conditions will actually change the color of the solution over time. As more product molecules enter the solution, the color intensity increases. This change in intensity can then be detected. Ex. 14, Stark Report ¶¶ 33-35. Note that had the hybridization event not occurred, the enzyme label attached to the probes would not be present

after the washing step and would not act on the substrates. As a result, the color of the solution would remain unchanged, leading to the conclusion that the analyte (*e.g.*, the virus sequence) was not present in the blood or saliva sample.

Figure 9 depicts the foregoing principles in the context of the '373 patent. As shown, a nucleic acid sequence from the sample is fixed to the solid support. Hybridization, or binding, is detected by means of an enzyme attached to the probe that transforms the substrate into a product capable of freely diffusing throughout the solution. The soluble product is represented by the squares. After transformation and release by the enzyme, the product dissolves in solution and may be detected as a change in the color of the solution. Ex. 14, Stark Report ¶¶ 44-46.

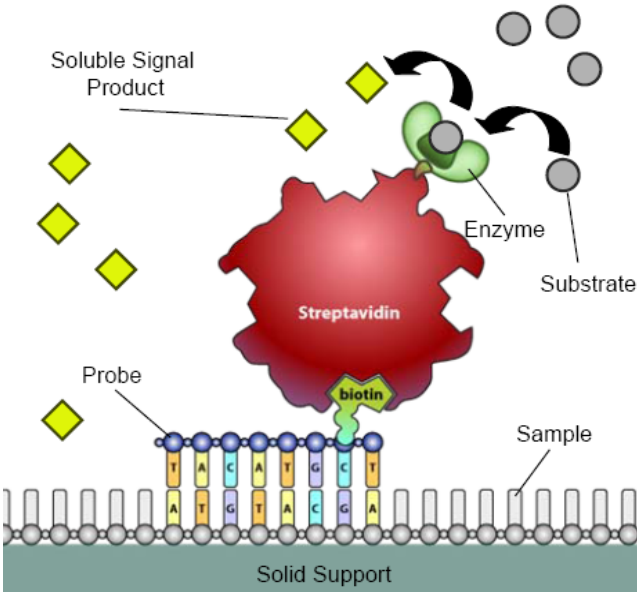


**Figure 9**

**b) Nucleic Acid Microarrays Rely On Fixed Probes And Localized Signals In The Form Of Tethered Fluorescent Molecules**

One potential disadvantage of the enzyme labels described above is that they produce a signal that is soluble, rather than localized. That is, the detectable product compounds diffuse through the assay solution and away from the site where the enzyme label is immobilized. When it is critical to know precisely where the binding of the analyte to the probe is taking place, a test

must be designed to generate a localized signal. This is the case with products known as microarrays.

First sold commercially in the mid 1990's, microarrays most commonly use a format in which tens of thousands of different unlabeled nucleic acid sequences designed as probes are placed at specific locations on a single glass substrate, such as a slide. Microarrays can be used to simultaneously detect many thousands of different analyte sequences from a single sample. Ex. 14, Stark Report ¶ 43.

As shown in Figure 10 below, the binding of probes with nucleic acid sequences from a sample is detected on commercial microarrays through use of tethered fluorescent labels, which do not diffuse into solution. Specifically, the sample nucleic acid sequences to be tested are labeled (instead of the probes) with fluorescent molecules and introduced in a solution into the microarray, where the sample sequences will bind with any complementary probe sequences. After the binding step and a washing step to remove any unbound sample sequences, all probe locations are examined for a signal generated from the detectable label tethered to a sample sequence bound to a probe. The detection of a signal from a probe location indicates the sample contains an analyte sequence that the probe was designed to detect, i.e., bind to. The absence of a signal from a probe location indicates the sample contains no analyte that the particular probe at that location was designed to detect.

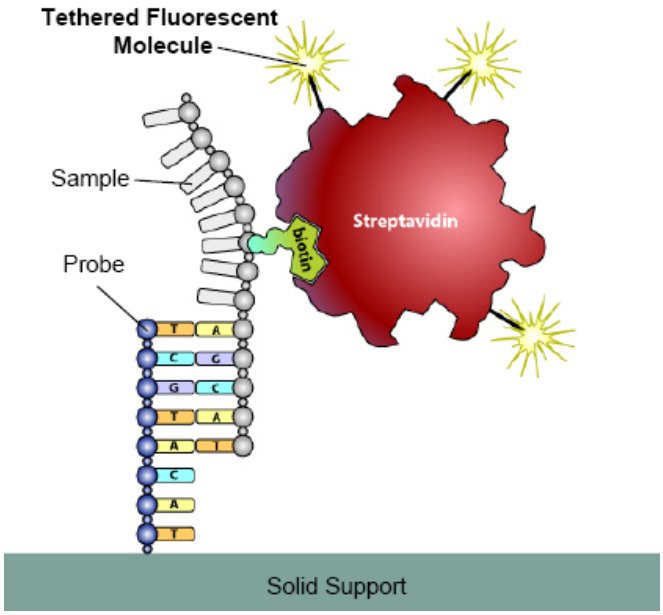


**Figure 10**

To function properly, each of the many thousands of different probe nucleic acid sequences must be attached to the substrate surface at a specific location. Nucleic acid sequences from the sample to which a detectable label have been added are introduced into the microarray in a solution, and may bind to certain of the probes, but not others. Because the individual probe locations are typically on a flat surface and do not include any barriers between them, it is critical that the detectable signals remain localized at each site where a labeled analyte from a sample has bound to a probe. Thus, if a signal is detected in the upper left hand corner of the array, it signals the presence of a particular analyte associated with the probe fixed to that location. But if a signal is detected in the lower right hand corner, it will signal the presence of a different analyte associated with a different probe fixed to the different location. If the detectable signals were able to freely diffuse across the surface of the glass substrate in a solution, it would destroy the location information that is essential for identifying which of the many thousands of differently located probes had bound to the labeled analyte sequences. Thus,

a soluble signal cannot be used on this type of a hybridization assay. Ex. 14, Stark Report ¶¶ 40-43.

### 2. *The Court's Constructions Of The Relevant Claim Terms Of The '373 Patent*

Claim 1 of the '373 patent recites:

> A method for *detecting a polynucleotide sequence* which comprises:
>
> *fixing said polynucleotide sequence to a solid support* which comprises or is contained within a transparent or translucent, non-porous system, such that a single-strand of the polynucleotide is capable of hybridizing to complementary nucleic acid sequences;
>
> *forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label* further comprising a signaling moiety capable of generating a *soluble signal*; and
>
> *generating and detecting said soluble signal*.

Ex. 10, '373 Patent, Claim 1. Claims 17, 18 and 25 are dependent on, and thus incorporate all limitations of, claim 1. *See* 35 U.S.C. §112 ¶ 4.[20]

The Court's Construction of the Format Requirement: The test method described in claim 1 requires "*fixing said polynucleotide sequence to a solid support*" and "forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, *said probe having attached thereto a chemical label*."[21] Enzo argued that this claim language should be read to permit either the analyte from the sample or the probe to be fixed to the solid support and to permit either the analyte or the probe to be labeled. The Court rejected

[20] The parties agreed that claims 17, 18 and 25 required no claim constructions independent of those given to Claim 1. Ex. 16, Claim Construction Order at 18. n.21.

[21] The '373 patent defines an "analyte" as "[a] substance . . . whose presence is to be detected and, if desired, quantitated." Ex. 10, '373 patent, col. 1:27-34; *see also* Ex. 16, Claim Construction Order at 20. A "probe" is defined as a "labeled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide of a particular analyte and which hybridizes to said analyte sequence." Ex. 10, '373 patent col. 1:42-45.

Enzo's contention and agreed with Defendants that those claim limitations required the specified test format whereby "the sample, which is the substance within which one is looking for the analyte, must be fixed to the solid support, and the probe, which is a labeled sequence complementary to the analyte, cannot be so fixed." Ex. 16, Claim Construction Order at 20, 24. As required by the plain language of the claims, the Court noted that "the patent requires that the probe be labeled." *Id*. at 20. The Court also expressly held that the claims do not cover a test method that requires "attaching the probe to the solid surface." *Id*. at 19.

The Court's Construction of "Soluble Signal": As noted above, claim 1 of the '373 patent also requires generation of a "soluble signal." Enzo argued that this term should include "any signal, including light, that does not form a precipitate." The Court rejected Enzo's contention and agreed with Defendants that claim 1 and its dependent claims "require, in their use of a 'soluble signal,' the creation of a soluble, or uniformly dispersed, product which generates a detectable signal." Ex. 16, Claim Construction Order at 24. The Court expressly found that neither light emanating from a label nor "a tethered fluorescent molecule" constituted a "soluble signal" within the meaning of claim 1 of the '373 patent: "As such, tethered fluorescent molecules and other signals generated by non-dissolved molecules are outside the scope of this claim." *Id*. at 20-22; *see also id*. at 21 n.24 (citing with approval Dr. Stark's testimony that "it does not make any sense whatsoever to talk about whether light is soluble.").

### 3. *The Accused Products Do Not Infringe The '373 Patent Under The Court's Claim Constructions*

#### a) The Accused Products Do Not Meet The "Format" Requirement Either Literally Or As Equivalents

The Court's claim construction requires that the sample be fixed to a solid support, and that the probe, which is labeled, cannot be so fixed. There is no factual dispute about the operation of each of the accused products. In each, the sample (and not the probe) is labeled and

the probes (and not the sample) are fixed.[22] Therefore, straightforward application of the claim language as construed requires the entry of summary judgment of non-infringement. Indeed, based on the declaration of Enzo's expert, Dr. Perkins, and Enzo's prior briefing on the issue, there does not appear to be any dispute that the accused products do not literally infringe the format requirement.

Enzo instead argued that the accused products infringe the asserted claims of the '373 patent under the doctrine of equivalents. Ex. 38, 5/14/07 Enzo Opp. at 18. But that argument is directly contrary to the Court's ruling that the claims do not cover a test format in which the probe is attached to the solid surface and/or the sample is labeled. Ex. 16, Claim Construction Order at 19-20. Enzo's attempt to ignore the Court's claim construction fails as a matter of law.

*First*, an unlabeled probe attached to a solid support that is contacted with a labeled sample (as in the Defendants' products) is the ***opposite*** of the test format required by the claims. Under the all elements rule and the specific exclusion principle, it is well settled that where "the scope of the claim was limited in a way that plainly and necessarily excluded a structural feature that was the opposite of the one recited in the claim, that different structure could not be brought within the scope of patent protection through the doctrine of equivalents." *SciMed*, 242 F.3d at 1346. Thus, the accused products cannot be infringing because to find otherwise would vitiate the plain language of claim 1 and allow Enzo to recapture claim scope that was specifically excluded by the Court. *See Asyst Techs.*, 402 F.3d at 1195 (holding that the term "mounted" can fairly be said to specifically exclude objects that are "unmounted").

*Second*, there is no dispute that there are substantial differences between the operation, structure and capability of the accused products, in contrast to the method of '373 claim 1, which also precludes a finding of infringement under the doctrine of equivalents. *See, e.g.*, *Wang*

[22] Ex. 36, McGall Decl., ¶¶4, 6-7; Ex. 24, Burczak Decl., ¶¶20-21, 32, 39, 44, 47, 49; Ex. 25, Mayer Decl., ¶¶30-31; Ex. 32, Will Decl., ¶3. Many of the accused products are kits for labeling samples. Ex. 36, McGall Decl., ¶¶4, 7; Ex. 24, Burczak Decl., ¶¶20-21, 39, 47; Ex. 32, Will Decl., ¶3.

*Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1385-86 (Fed. Cir. 1999). In connection with claim construction, the Court found that "because the patent requires that the probe be labeled, it would be impossible to conduct this test with the probe fixed to the solid support (as in a microarray), since to do so would result in false positives." Ex. 16, Claim Construction Order at 20 (citing testimony of Dr. George Stark); *see also* Ex. 36, McGall Decl., ¶10. In addition, the configuration of the accused products—unlabeled probe attached to solid support and labeled sample free-floating before hybridization—enhances mass production and enables complicated experiments that would not be possible using the claimed format. *See* Ex. 36, McGall Decl., ¶¶9, 11. This demonstrates the substantially different capabilities of the accused products as compared to claim 1 of the '373 patent.[23]

*Third*, the doctrine of equivalents cannot be used to recapture subject matter disclosed in a patent specification that was not claimed. *PSC Computer*, 355 F.3d at 1355-56 (cited with approval in *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005)). In *PSC Computer*, the Federal Circuit held that disclosed but unclaimed "plastic molded parts" were dedicated to the public when only metal parts were claimed. In its claim construction briefs, Enzo cited an example in the specification of the '373 patent as evidence that the claims cover the accused products. The Court expressly ruled, however, that "[a]lthough [Example 5] indicates that '[t]he advantages of this invention are also obtainable when the probe is immobilized on a non-porous plastic surface,' as explained above, the language of the patent places that setup for the test outside the scope of claim 1." Ex. 16, Claim Construction Order at 20, n.23. Because Enzo not only failed to claim the probe-immobilized format, but also claimed the opposite format, the disclosed but unclaimed subject matter relating to the probe-

[23] In its earlier opposition brief, Enzo relied on its expert, Dr. Perkins, to support the proposition that the "probe" and "analyte" are interchangeable. That approach plainly ignores the separate requirement imposed by the Court that the "probe" must be "labeled." *See* Ex. 37, Perkins Decl., ¶43; Ex. 16, Claim Construction Order at 20. The Court should therefore disregard Dr. Perkins' improper application of the function-way-result test. *See Arthur A. Collins, Inc. v. Northern Telecom, Ltd.*, 216 F.3d 1042, 1047 (Fed. Cir. 2000) (improper expert opinion "may not avoid summary judgment").

immobilized format used by the accused devices, is dedicated to the public. The doctrine of equivalents cannot be used to recapture subject matter that was dedicated to the public.[24]

**b) The Accused Products Do Not Meet The "Soluble Signal" Requirement Either Literally Or As Equivalents**

The Court's construction of "soluble signal" requires "the creation of a soluble, or uniformly dispersed, product which generates a detectable signal." In contrast, it is undisputed that Defendants' accused products utilize tethered fluorescent molecules, a fact that Enzo's expert, Dr. Perkins, has conceded. Ex. 37, Perkins Decl., ¶27.[25] This undisputed fact is fatal to Enzo's case because the Court expressly found that tethered molecules are not soluble and thus are outside the scope of the patent claims. *See* Ex. 16, Claim Construction Order at 22, 24.

Enzo nevertheless continued to battle with the Court's claim construction by contending that "[t]he soluble product generating the detectable signal, required by the '373 patent and practiced by Defendants' products, is the hybridized polynucleotide sequence having a label bound to one sequence." Ex. 38, 5/14/07 Enzo Opp. at 21. That argument improperly conflates the "probe" of the '373 claims with the "soluble product" required by the Court's claim construction. In any event, Enzo's argument wholly ignores the Court's ruling that the product generating the detectable signal must be ''uniformly dispersed" in solution, which the "hybridized polynucleotide sequence" is not. Ex. 16, Claim Construction Order at 22, 24.

[24] Enzo's infringement allegations as to dependent claims 17, 18 and 25 fall with its allegations as to independent claim 1. That is because dependent claims "shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. § 112(4). It is well-established that dependent claims are not infringed (either literally or under the doctrine of equivalents) where there is no infringement of the claims from which they depend. *See, e.g.*, *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989); *Deering Precision Instr., LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003).

[25] *See also* Ex. 36, McGall Decl., ¶13; Ex. 25, Mayer Decl., ¶33; Ex. 24, Burczak Decl., ¶¶31, 43, 48; Ex. 32, Will Decl., ¶4. PE's accused MicroMax products do not infringe for the additional reason that they form precipitates which are dry read. Ex. 25, Mayer Decl., ¶33. Enzo has specifically disclaimed precipitates as falling within the scope of '373 patent, claim 1. Ex. 16, Claim Construction Order at 20.

Because neither Enzo nor its expert Dr. Perkins advanced a legally cognizable argument under the doctrine of equivalents, the Defendants' demonstration that the accused products do not infringe the "soluble signal" limitation stands unrebutted.[26]

### F. Enzo's Patent Claims Against Certain Products Are Barred By Distributor Agreements Authorizing The Sale Of Those Products

Roche and PE are entitled to summary judgment of non-infringement of Enzo's patents as to certain accused products because those products were the subject of distributor agreements with Enzo. It is a fundamental principle of patent law that an infringement claim must be premised on the *unauthorized* manufacture, sale, and/or use of a product embodying the claimed invention. Roche and PE each had written distributor agreements with Enzo that expressly granted them the right to manufacture, sell, and distribute products that Enzo now accuses of infringing its patents. Regardless of whether one characterizes the grant as a grant of authority or as a license, the result is the same—Enzo cannot assert patent infringement claims against products that Roche and PE were authorized to manufacture and sell in the United States.[27]

#### 1. *Authorized Acts Cannot Be The Subject Of Claims Of Infringement*

A patentee's basic right is defined by statute as "the right to exclude others from making, using, or selling the invention throughout the United States." 35 U.S.C. § 154(a)(1). That right

[26] Dr. Perkins argued that "[t]he overall function of claim 1 of the '373 patent is to detect and quantitate the presence of a polynucleotide sequence." Ex. 37, Perkins Decl., ¶27 (emphasis in original). If that is an attempt at a doctrine-of-equivalents argument, it is meritless, as function-way-result evidence under the doctrine must be presented on an element-by-element basis, not on the basis of the claim as a whole. *See, e.g., Aquatex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1328 (Fed. Cir. 2007). Dr. Perkins also argues that the '373 patent "leaves open the possibility of tethering a fluorescent moiety directly to the polynucleotide." Ex. 37, Perkins Decl., ¶27. That ignores the Court's ruling that the prior art references in the '373 patent are consistent with the fact that a fluorescent signal originating from a tethered molecule is not "soluble." Ex. 16, Claim Construction Order at 21 n.25. *See Asyst Techs.*, 402 F.3d at 1195 (claim scope specifically excluded by court).

[27] In its March 2005 interrogatory responses, Enzo accused a number of Amersham Gene Images and ECL products sold pursuant to Amersham's distributorship agreement with Enzo of infringing '824 claim 1, '767 claim 42 and '928 claim 1. Enzo dropped those allegations in its September 2006 interrogatory response as it did not accuse those products of infringing any specific patent claims. Regardless, payment under the agreement would have been a complete defense to alleged infringement.

is enforceable through an infringement action against any person "who[] *without authority* makes, uses, offers to sell, or sells any patented invention." *Id*. § 271(a) (emphasis added); *see also McCoy v. Mitsubishi Cutlery, Inc.*, 67 F.3d 917, 920-21 (Fed. Cir. 1995) ("To enforce the contracts of the patentee, the law may imply a license where a patent holder sells or authorizes the sale of a patented product—a voluntary sale.").

A "license" is nothing more than "permission" or "authority" to commit some act that would otherwise be unlawful and/or invade upon another's property rights. Ex. 39, Black's Law Dictionary 1002 (9th ed. 2009). As the Supreme Court noted in *De Forest Radio Telephone & Telegraph Co. v. United States*,

> No formal granting of a license is necessary in order to give it effect. Any language used by the owner of the patent or any conduct on his part exhibited to another, from which that other may properly infer that the owner consents to his use of the patent in making or using it, or selling it, upon which the other acts, constitutes a license, and a defense to an action for a tort.

273 U.S. 236, 241-42 (1927) (existence of license, even if implied, is complete defense to action for infringement); *see also Wang Labs., Inc. v. Mitsubishi Elecs. Am. Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997) ("In patent law, an implied license merely signifies a patentee's waiver of the statutory right to exclude others.").

The essence of a distribution agreement is an authorization to manufacture and/or sell the patented product. As the Federal Circuit held in *Genetic Implant Systems, Inc. v. Core-Vent Corp.*, "[t]he appointment of a distributor to sell a product covered by a patent is analogous to a grant of a patent license. Such an action conveys an implied license to the distributor, thereby surrendering the patentee's right to exclude the distributor under the patent." 123 F.3d 1455, 1458 (Fed. Cir. 1997); *cf. Asset Mktg. Sys. Inc. v. Gagnon*, 542 F.3d 748, 754-55 (9th Cir. 2008) (citing authority for the rule that a license is implied where the parties intended the copyrighted work to be distributed by the defendant); *Brown v. Ames*, 201 F.3d 654, 661 (5th Cir. 2000) ("[C]ommon law on the right of publicity appears ordinarily to permit an authorized publisher or distributor to use name or likeness to identify truthfully the author or creator of the goods").

In prior briefing on this issue, Enzo argued that the distributor agreements expressly provide that the "relationship between" Roche and PE on the one hand, and Enzo is that of "seller and buyer" and that the agreements did not constitute or imply a license to Enzo's patents. Ex. 40, Roche Agreement Art. XI; Ex. 31, PE Agreement ¶ 2. That argument proves nothing. Neither Roche nor PE claims to have acquired a broad and unqualified license to practice Enzo's patents. Their only argument is, consistent with both logic and case law, that they were expressly authorized to manufacture and sell the products covered under the distribution agreements, and having granted them that authority, Enzo has no right to sue them for patent infringement for exercising that authority. "That interpretation is in accordance with the basic contract law principle that a party may not assign a right, receive consideration for it, and then take steps that would render the right commercially worthless." *Jacobs v. Nintendo of Am., Inc.*, 370 F.3d 1097, 1101 (Fed. Cir. 2004) (finding an implied license as to the sale of products authorized in a settlement agreement). Any other interpretation would lead to the nonsensical result that Roche and PE could be liable for patent infringement simply by virtue of the exercise of their contractual rights and obligations under the distributor agreements.

Alternatively, the same result is reached under Enzo's characterization of the relationship as one of "seller and buyer" through the application of the "patent exhaustion" doctrine. *See Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1350 (Fed. Cir. 2003) (patent exhaustion is "closely related . . . to the grant of an implied license."); *BR-111 Imports & Exports, Inc. v. Indusparquet Industria E Comercio De Madeiras LTDA*, No. 10-22206-Civ, 2010 WL 4317021, at *7-8 (S.D. Fla. Sept. 23, 2010) ("The distributors that purchased the displays appear to be protected by the exhaustion doctrine."). "The longstanding doctrine of patent exhaustion doctrine provides that the initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Computer, Inc. v. LG Elecs., Inc.,* 553 U.S. 617, 625 (2008); *see also Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("[A]n authorized sale of a patented product places that product beyond the reach of the patent."). Although PE always

made all of the products that it sold under the distribution agreement (and Roche made most of them), if the distribution agreements are viewed as creating a buyer/seller relationship, then the purchase by the buyer (PE/Roche) from the seller (Enzo) exhausts the seller's patent rights. The rationale underlying the patent exhaustion and implied license doctrines is the same—the patent holder has received his reward for his inventive work in the sale of the patented product. *McCoy,* 67 F.3d at 921.

### 2. *Enzo's State Law Claims Have No Bearing On Its Claims For Patent Infringement*

Roche was authorized to sell thirteen of the accused products pursuant to a 1994 distribution agreement with Enzo to distribute and sell to the research market certain "PRODUCTS," defined as products "covered by" certain Enzo patents. Ex. 40, Roche Agreement at 1-3; Ex. 41, Enzo's First Amended Answer and Counterclaims ¶ 49. Roche distributed and sold those products, as it was authorized, and it paid Enzo over $23 million under the agreement. Ex. 42, Togonal Decl., ¶4. Roche continuously made payments to Enzo under the distribution agreement, and detailed its sales of those fourteen products (among others) in quarterly written reports to Enzo. *Id*. ¶¶5-7, Ex. A.

Similarly, PE's "distributorship agreement" granted it the right to sell certain specific products that were identified on Exhibit C to the agreement. Ex. 31, PE Agreement ¶ 1. PE developed, manufactured and sold all of the products listed on Exhibit C and paid Enzo a "transfer price" based on the amount of product sold. LeBlanc Decl., ¶¶6-8.[28] With the exception of the AcycloPrime and Micromax products, the PE products accused of infringement are all products for which PE has paid, and Enzo has accepted, more than $15 million. *See* Ex. 43, Finguerra Decl. Ex. 1; Ex. 44, LeBlanc Decl., ¶12.

[28] PE terminated the agreement when the Ward patents expired at the end of 2004 and ceased selling the small number of Exhibit C products that are accused of infringing the '060 patent, which expires in 2010. Ex. 44, LeBlanc Decl., ¶11; Ex. 25, Mayer Decl., ¶¶35-37.

Enzo previously argued that the payments made by Roche and PE were "inadequate" under the terms of their respective distribution agreements, apparently suggesting that it did not receive all of the payments to which it was entitled. *See* Ex. 38, 5/15/07 Enzo Opp. at 23. Although there is no merit to Enzo's allegations, they are, in any event, breach of contract claims, irrelevant to the issue of patent infringement. *Tessera, Inc. v. International Trade Comm'n,* 646 F.3d 1357, 1370 (Fed. Cir. 2011) (patent rights exhausted whether or not licensee defaulted on payments).[29] Enzo also complained that Roche and PE did not make payments after 2004, but it is axiomatic that an expired patent cannot be infringed. *See Lans v. Digital Equip. Corp.*, 252 F.3d 1320, 1328 (Fed. Cir. 2001). All of the patents at issue except the '060 patent expired at the conclusion of 2004. As to the '060 patent, Roche is not accused of infringing that patent and PE stopped selling the products accused of infringing that patent when it terminated its distributorship agreement.

## V. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT ON ENZO'S LANHAM ACT CLAIM

Enzo has alleged that PE, Amersham, Orchid and MPI have each committed unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). No further specifics or supporting facts are provided for these allegations in any of the Complaints, but Enzo's president, Barry Weiner, testified that the core of the allegations was Defendants' marketing of "products

[29] This construction is supported by express language in each contract. For example, the PE distribution agreement devotes a separate paragraph to the consequences of a termination of the Agreement, including a termination for uncured breach of both payment and distribution terms. Ex. 31, PE Agreement at ¶ 15. This paragraph provides for the immediate cancellation of the distribution and manufacturing rights previously granted, the retroactive rendering "null and void" of any prior stipulation or admission made by PE about Enzo's patents, and the reaffirmation of each party's rights in its respective intellectual property. There is no suggestion in the paragraph that a termination of the Agreement, even for uncured material breach, would suddenly and retroactively render PE's prior distribution and manufacturing infringing. In fact, any other result would be practically and commercially untenable. The Roche agreement also specifically provides for notice and cure in the case of non-payment or other breach, Ex. 40, Roche Agreement at Art. XIV, and similarly includes no suggestion that a termination for uncured breach would somehow retroactively expose Roche to patent infringement claims for prior exercise of its manufacturing and distribution rights.

utilizing Enzo technology covered under issued patents" without listing Enzo's patents on their respective marketing materials. Ex. 45, Weiner Dep. Tr. 39. As a matter of law, however, a failure to give attribution to patent ownership is not a false or misleading representation of fact under Section 43(a) of the Lanham Act.[30]

Essential to an action under Section 43(a)(1) of the Lanham Act is the use of a "word, term, name, symbol, or device … or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact" *on or in connection with any goods or services*. 15 U.S.C. § 1125(a). To the extent Enzo is asserting that patents are considered goods or services under the Lanham Act, the case law is clear that they are not, and that the failure to provide proper attribution is not considered a violation of 43(a)(1). *See Invista S.a.r.l. v. E.I. Du Pont de Nemours & Co.*, No. 08 Civ. 7270(BSJ), 2008 WL 4865208, at *3-4 (S.D.N.Y. Nov. 3, 2008); *Hans-Jürgen Laube & Oxidwerk HJL AG v. KM Europa Metal AG*, No. 96 Civ. 8147 (PKL), 1998 WL 148427, at *2 (S.D.N.Y. Mar. 27, 1998) (citing *Tubeco, Inc. v. Crippen Pipe Fabrication Corp.*, 402 F. Supp. 838, 848 (E.D.N.Y. 1975)); *digiGAN, Inc. v. iValidate, Inc.*, No. 02 Civ. 420 (RCC), 2004 WL 203010, at *4-5 (S.D.N.Y. Feb. 3, 2004).

Following the closure of discovery, Enzo sought to recast its Lanham Act claim as one of "reverse passing off." *See* Ex. 38, 5/14/07 Enzo Opp. at 38-39. Leaving aside that it was too late for Enzo to assert new claims, the recasting of the claim does nothing to further Enzo's case. It is well settled that conduct violating Section 43(a)(1)(A) must concern the "origin, sponsorship, or approval" of the actual producer of the goods or services giving rise to the claim. 15 U.S.C. § 1125(a)(1)(A); *see also Baden Sports, Inc. v. Molten USA, Inc.*, 556 F.3d 1300, 1306 (Fed. Cir. 2009). The Supreme Court has held that "origin of goods" under this section of the Lanham Act "does not refer to 'the person or entity that originated the ideas or communications that 'goods' embody or contain.'" *Id.* (citing *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 32 (2003)). Rather, "'origin

[30] Summary judgment of non-infringement of Enzo's patents by Defendants' accused products also mandates summary judgment on any corresponding attribution claims.

of goods' [refers] 'to the producer of the tangible goods that are offered for sale, and not to the author of any idea, concept or communication embodied in those goods.'" *Id*. (citing *Dastar*, 539 U.S. at 37). Additionally, any action for false advertising under 43(a)(1)(B) must concern misrepresentations as to "the nature, characteristics, qualities, or geographic origin" of the subject goods or services themselves. 15 U.S.C. § 1125(a)(1)(B); *see also Baden Sports*, 556 F.3d at 1306.

It is uncontroverted that all of the accused products were manufactured by and originated with Defendants. Nor has Enzo even suggested (nor could it) that any of the defendants misrepresented the nature, qualities or characteristics of any of the accused products. Thus, any claim under Section 43(a)(1)(B) concerning the "origin, sponsorship or approval" of the accused goods" or the "nature, characteristics, qualities, or geographic origin" of any of Defendants' goods or services cannot be sustained. *See Baden Sports*, 556 F.3d at 1307 (plaintiff cannot "avoid the holding in *Dastar* by framing a claim based on false attribution of authorship as a misrepresentation of the nature, characteristics, and qualities of a good.").

Accordingly, summary judgment should be entered on Enzo's Lanham Act claims.

## VI. CONCLUSION

For the foregoing reasons, the Court should grant the Defendants' motion for summary judgment of non-infringement of the '824, '767, '373, '040, '060 and '955 patents and for summary judgment in favor of Defendants on Enzo's Lanham Act claims.

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Respectfully submitted,

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